UNITED STATES PATENT AND TRADEMARK OFFICE

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09/992,035	11/23/2001	Michael D. Dahlin	1039-0030	4451

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ART UNIT	PAPER NUMBER
3686	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	09/992,035	DAHLIN ET AL.
	Examiner	Art Unit
	SHEETAL R. RANGREJ	3686

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>30 September 2008</u>.
2a)☒ This action is **FINAL**.   2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1,4-9,18,21-25,27,41-54 and 59-62</u> is/are pending in the application.
     4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) <u>1, 4-9, 18, 21-25, 27, 41-54, and 59-62</u> is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
     a)☐ All   b)☐ Some * c)☐ None of:
       1.☐ Certified copies of the priority documents have been received.
       2.☐ Certified copies of the priority documents have been received in Application No. _____.
       3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
     * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)
1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO/SB/08)
     Paper No(s)/Mail Date _____.
4)☐ Interview Summary (PTO-413)
     Paper No(s)/Mail Date. _____.
5)☐ Notice of Informal Patent Application
6)☐ Other: _____.

DETAILED ACTION

Prosecution History Summary

1.   Claims 2-3, 10-17, 19-20, 26, 28-40, and 55-58 are cancelled.

2.   Claims 1, 4-9, 18, 21-25, 27, 41-54, and 59-62 are pending.

Claim Objections

3.   Claim 59 is objected to because of the following informalities: shows amending the

claim but the identifier of the claim discloses "previously presented". Appropriate correction is

required.

Claim Rejections - 35 USC § 103

4.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5.   Claims 1, 4-5, 8-9, 18, 21-22, 25, 27, 41-51, 53-54, and 59-62 are rejected under 35

U.S.C. 103(a) as being unpatentable over Barry et al., U.S. Patent No. 6,188,988 in view of

Martin et al., U.S. Patent No. 6,484,144.

6.   As per claim 1, Barry teaches a system to implement at least one medical diagnostic or

treatment algorithm in a healthcare workflow, the system comprising: storage including a first

medical diagnostic or treatment algorithm, the first medical diagnostic or treatment algorithm

including a selection rule associated with a medical finding, and a second diagnostic or treatment algorithm, the second medical diagnostic or treatment algorithm including a selection rule associated with a medical finding (**Barry: col. 11, 65 to col. 12, 2**); a user interface operable to display an interface associated with the healthcare workflow to a healthcare provider, wherein the healthcare workflow includes a set of interfaces for the healthcare provider to enter patient medical data into the at least one patient medical record during a patient encounter, the patient medical data to indicate the medical finding (**Barry: column 12, line 61 – column 13, line 9**); a disease management engine operable to select one medical diagnostic or treatment algorithm from the first medical diagnostic or treatment algorithm or the second medical diagnostic or treatment algorithm based on the at least one patient medical record and operable to modify the healthcare workflow in accordance with the at least one medical diagnostic or treatment algorithm based on the patient medical data (**Barry: column 13, lines 25-30**); and wherein the first and second medical diagnostic or treatment algorithms are stored prior to the patient encounter (**Barry: col. 8, 12-26**).

7.   Although Barry teaches at least one patient medical record (**Barry: column 12, 61 to col. 13, 9**). Barry does not explicitly teach that the medical record includes an indicator associated with one third-party payer. Martin teaches a medical record includes an indicator associated with one third-party payer (**Martin: col. 9, 14-20**).

        Although the treatment regimens of Barry are associated with a plurality of factors including cost (**Barry: column 13, lines 30-32**), Barry does not explicitly teach that they are associated with a first third-party payer or a second third-party payer. Martin teaches a method

of selecting a treatment plan for a patient that includes associating third-party payers with

treatment plans for the purpose of selecting an appropriate treatment plan (**Martin: column 15,**

lines 55-60).

It would Although Barry teaches a disease management engine operable to select one medical

diagnostic or treatment algorithm based on the medical record, Barry does not explicitly teach

that selecting medical diagnostic or treatment algorithm is based on the indicator associated with

the one third-party payer (**Martin: col. 15, 55-60; col. 16, 6-26**).

It would have been obvious to one of ordinary skill in the art at the time of the invention

to incorporate such association for analysis into the system of Barry. One of ordinary skill in the

art would have been motivated to incorporate such a feature for the purpose of providing higher

quality, more effective, and lower cost healthcare (**Martin: column 4, lines 50-53**).

8.   As per claim 4, Barry teaches the system of claim 1 as described above. Barry further

teaches the modification of the healthcare workflow is represented by the display of a banner

(**Barry: column 16, lines 13-20**, the Examiner is interpreting the pop-up "Change Therapy

Recommendation" message box to be a form of "banner" as recited).

9.   As per claim 5, Barry in view of Martin teaches the system of claim 1 as described above.

Barry further teaches the modification of the healthcare workflow is represented by the display

of a highlighted choice (**Barry: Figure 6B**, it is noted that the adjusted dosage is indicated by a

'+' sign).

10.   As per claim 8, Barry in view of Martin teaches the system of claim 1 as described above.

Barry further teaches the modification of the healthcare workflow is represented by the display

of a recommended step therapy (**Barry: column 13, lines 25-30**).

11.   As per claim 9, Barry in view of Martin teaches the system of claim 1 as described above.

Barry further teaches the user interface is a portable device (**Barry: column 9, lines 55-59**, the

Examiner interprets a computing device having minimal hardware to be portable).

12.   As per claim 41, Barry in view of Martin teaches the system of claim 1 as described

above. As described above, Barry does not explicitly teach a third party payer. Martin further

teaches the first third-party payer is a prescription benefits management company, an HMO, or

an insurance company (**Martin: column 15, lines 55-60**). It would have been obvious to one of

ordinary skill in the art at the time of the invention to incorporate such a feature into the system

of Barry for the reasons given above with respect to claim 1.

13.   As per claim 42, Barry in view of Martin teaches the system of claim 1 as described

above. As described above, although Martin teaches that third-party payers are insurance

companies, neither Barry nor Martin explicitly teach that the second third-party payer is a

government agency. The Examiner takes Official Notice that it was old and well known in the

art at the time of the invention that there were government agencies that served as a third-party

payer. For example, Medicare and Medicaid are old and well known examples of such

government third-party payers. Therefore, it would have been obvious to one of ordinary skill in

the art at the time of the invention to incorporate a third-party payer in the form of a government

agency within the combined teachings of Barry and Martin. One of ordinary skill in the art

would have been motivated to incorporate such an element for the purpose of providing more cost effective health care (see column 4, lines 50-53 of Martin).

14.   As per claim 43, Barry in view of Martin teaches the system of claim 1 as described above. Barry further teaches the at least one medical diagnostic or treatment algorithm includes an element **(Barry: col. 11, 38 to col. 12, 59)**.

15.   As per claim 44, Barry in view of Martin teaches the system of claim 43 as described above. Barry further teaches the element includes a task field, a condition field, and a content field **(Barry: col. 11, 38 to col. 12, 59**; including tables; i.e. dosage; medical conditions; rules).

16.   As per claim 45, Barry in view of Martin teaches the system of claim 44 as described above. Barry further teaches the disease management engine is operable to modify, based on a content field, the healthcare workflow **(Barry: column 13, lines 25-30)**.

17.   Claims 18 and 27 recite substantially similar limitations to those already addressed in claim 1 and, as such, are rejected for similar reasons as given above.

18.   As per claim 46, Barry in view of Martin teaches the system of claim 18 as described above. Barry further teaches modifying the interface includes presenting an approval interface associated with approval of a procedure based on a care plan **(Barry: column 13, lines 25-30)**.

19.   Claims 47-50 recite substantially similar additional limitations to those already addressed in claims 42-45 and, as such, are rejected for similar reasons as given above.

20.   Claims 51 and 54 recite substantially similar limitations to those already addressed in claims 1, 18, and 27 and, as such, are rejected for similar reasons as given above.

21.   Claim 53 recite substantially similar limitations as those already addressed in claim 46, and, as such, are rejected for similar reasons as given above.

22.   Claims 21-22 and 25 recite substantially similar additional limitations to those already addressed in claims 4-5 and 8 and, as such, are rejected for similar reasons as given above.

23.   As per claim 59, Barry teaches a method of performing a patient encounter, the method comprising: storing a plurality of treatment algorithms, each treatment algorithm including a task field, a condition field, and a content field, a first treatment algorithm of the plurality of treatment algorithms, the task field of the first treatment algorithm indicating a task, the condition field of the first treatment algorithm indicating a medical finding, a second treatment algorithm of the plurality of treatment algorithms, a task field of the second treatment algorithm indicating a task, a condition field of the second treatment algorithm indicating the medical finding (**Barry: col. 11, 38 to col. 12, 59**); receiving medical data from an interface device, the medical data associated with the patient and including the medical finding (**Barry: col. 12, 61, col. 13, 9**); selecting a treatment algorithm of the previously stored first treatment algorithm or the previously stored second treatment algorithm based at least in part on the indicator of the first patient medical record and based at least in part on the medical finding (**Barry: col. 13, 25-30**); modifying a medical input template associated with the task based on the content field of the selected treatment algorithm of the first or second treatment algorithms (**Barry: col. 13, 25-30**); and providing the modified input template to the interface device (**Barry: col. 13, 25-30**).

24.   Although Barry teaches at least one patient medical record (**Barry: column 12, 61 to col. 13, 9**). Barry does not explicitly teach that the medical record includes an indicator associated

with one third-party payer. Martin teaches a medical record includes an indicator associated with one third-party payer (**Martin: col. 9, 14-20**).

Although Barry teaches at least one patient medical record (Barry: column 12, 61 to col. 13, 9). Barry does not explicitly teach that the medical record includes an indicator associated with one third-party payer. Martin teaches a medical record includes an indicator associated with one third-party payer (**Martin: col. 9, 14-20**).

Although the treatment regimens of Barry are associated with a plurality of factors including cost (**Barry: column 13, lines 30-32**), Barry does not explicitly teach that they are associated with a first third-party payer or a second third-party payer. Martin teaches a method of selecting a treatment plan for a patient that includes associating third-party payers with treatment plans for the purpose of selecting an appropriate treatment plan (**Martin: column 15, lines 55-60**).

25.   Claim 60 recite substantially similar limitations as those already addressed in claim 59, and, as such, are rejected for similar reasons as given above.

26.   As per claim 61, the method of claim 18 is as described. Barry further teaches wherein the one medical diagnostic or treatment algorithm includes an algorithm template, and wherein modifying the interface displayed to the healthcare provider including modifying a medical input template based on the algorithm template (**Barry: col. 13, 53, col. 14, 25**).

27.   Claim 62 recite substantially similar limitations as those already addressed in claim 61, and, as such, are rejected for similar reasons as given above.

28.   <u>Claims 6, 23, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over</u>

<u>Barry et al., U.S. Patent No. 6,188,988 in view of Martin et al., U.S. Patent No. 6,484,144 and</u>

<u>further in view of Iliff, U.S. Patent No. 6,206,829</u>.

29.   As per claim 6, Barry in view of Martin teaches the system of claim 1 as described above.

Barry does not explicitly teach the modification of the healthcare workflow is represented by the

display of a question. Iliff teaches a medical treatment advice system that includes displaying to

a user a modification of a healthcare workflow represented by the display of a question (**Iliff:**

column 79, lines 59-63 and Figure 33). It would have been obvious to one of ordinary skill in

the art at the time of the invention to incorporate this feature into the system of Barry. One of

ordinary skill in the art would have been motivated to incorporate such a feature for the purpose

of aiding in selecting treatment regimens in which the information regarding the treatment

options can be readily understood (**Barry: column 2, lines 33-45**) by presenting a user with

additional questions as taught by Iliff.

30.   Claims 23 and 52 recite substantially similar additional limitations to those already

addressed in claim 6 and, as such, is rejected for similar reasons as given above.

31.   <u>Claims 7 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over</u>

<u>Barry et al., U.S. Patent No. 6,188,988 in view of Martin et al., U.S. Patent No. 6,484,144 and</u>

<u>further in view of Schmidt et al., U.S. Patent No. 6,839,678</u>.

32.   As per claim 7, Barry in view of Martin teaches the system of claim 1 as described above.

Although Barry does teach that the system may be used for clinical drug trial activities, the

reference does not explicitly teach the modification of the healthcare workflow is represented by

the display of a notification of a drug trial. Schmidt teaches automatically determining and

notifying a patient of eligibility for medical studies by a central server (**Schmidt: column 2,**

lines 9-19). It would have been obvious to one of ordinary skill in the art at the time of the

invention to incorporate this feature into the system of Barry. One of ordinary skill in the art

would have been motivated to incorporate such a feature for the purpose supporting the clinical

drug trial activities in Barry (**Barry: column 8, lines 1-5**).

33.   Claim 24 recites substantially similar additional limitations to those already addressed in

claim 7 and, as such, is rejected for similar reasons as given above.

Response to Arguments

34.   In the remarks filed 7/16/07, Applicant argues in substance that (1) neither Barry nor

Martin teaches associating separate disease management algorithms with different third-party

payers; (2) Barry fails to teach selecting one of the first or second medical diagnostic or

treatment algorithms; (3) Barry fails to teach a disease management algorithm including a

selection rule associated with medical finding and including an algorithm template; (4) Barry

fails to teach or suggest storing the first and second disease management algorithms prior to a

patient encounter (5) Barry in view of Martin fail to teach certain dependent limitations; (6)

Barry fails to teach a medical or diagnostic treatment algorithm including an element, the

element including a task field, a condition field, and a content field.

35.   In response to Applicant's argument (1), a noted in the arguments, the Examiner relied

upon the teachings of Martin for this limitation. However the Examiner respectfully maintains

that Martin teaches associating disease management algorithms with third-party payers. Martin
teaches comparing a given treatment plan to insurance coverage (i.e. third party payer) (see
column 15, line 55 – column 16, line 44). Such a comparison is a form of association. Having
multiple disease management algorithms associate with different third-party payers does not
change the invention as a whole and the association process of disease management algorithm to
a third-party payer would essentially be the same and therefore does not change the invention as
a whole; goes through the same process at associating disease management algorithm to a third-
party payer. Therefore, it is respectfully maintained that such a limitation, as recited in the
claims, is taught by Martin.

36.   In response to Applicant's argument (2), it is respectfully submitted that the Examiner is
interpreting the "inference engine" of Barry to be a form of "disease management engine" as
recited in the claims. At column 13, lines 25-39, Barry teaches suggesting a treatment regimen
by the inference engine. The suggested regimen is clearly selected form multiple therapies
because Barry indicates that if more than one drug therapy is presented, they can be ranked.
Therefore, the Examiner maintains that this limitation is taught by Barry.

37.   In response to Applicant's argument (3), it is respectfully submitted that the Examiner
states that the applicant merely makes a conclusatory statement regarding Barry not disclosing
(4) rather than providing support or evidence on how the prior art does not disclose the
applicant's claimed invention; therefore it is respectfully maintained that such a limitation, as
recited in the claims, is taught by Barry.

38.   In response to Applicant's argument (4), it is respectfully submitted that the Examiner states that the applicant merely makes a conclusatory statement regarding Barry not disclosing (4) rather than providing support or evidence on how the prior art does not disclose the applicant's claimed invention; therefore it is respectfully maintained that such a limitation, as recited in the claims, is taught by Barry.

39.   In response to Applicant's argument (5), the Examiner respectfully maintains that the cited portions of the references teach each of the dependent limitations given the broadest reasonable interpretation to one of ordinary skill in the art at the time of the invention. Accordingly, the Examiner does not find Applicant's arguments to be persuasive.

40.   In response to Applicant's argument (6), it is respectfully submitted that the Examiner is interpreting the rules presented in Table 3 to include task field, condition field, and content field providing a medical diagnostic or treatment algorithm. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the task field indicates to which task the algorithm is associated) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

41.   The prior art made of record and not relied upon is considered pertinent to applicant's

disclosure.

42.   **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time

policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing

date of this final action.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to SHEETAL R. RANGREJ whose telephone number is (571) 270-

1368. The examiner can normally be reached on M-F 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the

organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/SRR/
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